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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,339	05/17/2002	Paul Alexander Jones	217926USOPCT	6486

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,339	JONES ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3-22-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Amendment filed March 22, 2004 is acknowledged. Original claims 1-6 are canceled. New claims 7-11 are presented and represent all of the claims now under consideration.

Subsequent to the cancellation of the original claims, the objection under 37 CFR 1.75(c) and rejections under 35 U.S.C. 101 and 112, second paragraph, of record, are moot.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The abstract of the disclosure is objected to because it is not clearly drawn to the subject matter now claimed. Correction is required. See MPEP § 608.01(b).

Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The recitation in claim 9 "in which the brain damage caused by ischemia or hemorrhage is hemorrhage infarct (hemorrhagic infarct?), head injury, subarachnoid hemorrhage, intracerebral hemorrhage, cerebral thrombosis, cerebral embolism, cardiac arrest, stroke or transient ischemic attacks (TIA)" lacks clarity. Each condition, i.e., hemorrhage infarct, head injury, subarachnoid hemorrhage, intracerebral hemorrhage, cerebral thrombosis, cerebral embolism, cardiac arrest, stroke or transient ischemic attacks, may be a cause of brain damage. It is suggested -- which is the result of -- is inserted in claims 9-11 after "ischemia or hemorrhage".

Claims 7-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or practice the invention. The original claims were directed to the treatment or prevention of any acute or chronic cerebral neurodegenerative disease. The subject matter now under consideration is drawn to the treatment or prevention of brain damage caused by ischemia or hemorrhage, as well as conditions that cause the ischemia or hemorrhage. The specification provides support for cortical protection of the compound of formula I in the ET-1 model of stroke.

Applicants argue the present claims now contain the limitations of canceled claim 4 which was not subject to the rejection of record under 35 U.S.C. 112, first paragraph.

Original claim 4, and the independent claim from which it depended, were composition claims. Accordingly, they were not subject to the rejection of record under 35 U.S.C. 112, first paragraph, in the First Office Action

. Attention is directed to *In re Wands*, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to prevention or treatment of brain damage caused by ischemia or hemorrhage.

The relative skill of those in the art is generally that of a Ph.D. or M.D. with expertise in the area of neurology.

Each particular type of brain damage whether caused by an ischemic event or by hemorrhage often has its own specific characteristics and etiology. Brain damage may occur from both pathological processes, but very often does not. A successful treatment modality for ischemia does not presage successful treatment for hemorrhage. There are presently no absolutely successful therapies for the prevention of brain damage whether caused by ischemia or hemorrhage.

The breadth of the claims

The claims are broad and inclusive of many disorders that may cause brain damage.

The amount of direction or guidance provided and the presence or absence of

working examples

The working example is limited to the ET-1 model of stroke, the neuroprotective properties of which do not extrapolate to hemorrhage. There are no examples to support or suggest a successful therapeutic regimen.

The quantity of experimentation necessary

Applicants have failed to provide support for efficacy in the treatment or prevention of the various, and neurologically diverse, pathological conditions encompassed in the language of the claims. The skilled artisan would expect the interaction of a particular compound in the prevention or treatment of a particular neurological disorder to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for the administration of a particular compound. The instant specification sets forth no such understanding. No direction is provided to distinguish therapy among the various disorders. Absent reasonable *a priori* expectations of success for preventing any particular neurological disorder, one skilled in the art would have to test extensively many diverse neurological conditions to discover which particular disorder responds to the compound of instant formula I. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Applicants' arguments with respect to canceled claims 1-6 that were rejected in the last Office Action under 35 U.S.C. 102(b), have been considered but are moot in view of the new ground of rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-11 rejected under 35 U.S.C. 102(b) as being anticipated by Kelly et al., U.S. Patent 5,648,351.

Kelly teaches the administration of the macrolide of instant formula I wherein R^{10} may be alkyl substituted by =O for treating cerebral ischemic disease, particularly cerebral infarction. See the formula at the bottom of column 1, as well as column 2, line 11. Further, see column 8, lines 22-30, specifically encompassing head injury, subarachnoid hemorrhage, cerebral thrombosis, cerebral embolism, cardiac arrest, stroke, transient ischemic attacks and stroke. This disclosure is drawn to all macrolides in the reference.

No claim is allowed.

Applicants' Amendment necessitated the new grounds of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

October 6, 2005

Phyllis G. Spivack

1614

PHYLLIS SPIVACK
PRIMARY EXAMINER